INTERIM DRAFT
EPA REQUIREMENTS FOR QUALITY MANAGEMENT PLANS

EPA QA/R-2

Region 6 U.S. EPA
Quality Assurance Team

Dallas, Texas 75202

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NOTES

QUALITY MANAGEMENT PLANS

Introduction

This document incorporates the national U.S. EPA Requirements for Quality Management Plans and the Region 6 policy requirements into one document for ease of use by our customers.

It is both a Regulatory requirement and policy of EPA that all environmental programs conducted by or on behalf of EPA shall establish and implement effective Quality Systems. EPA policy requires that all organizational units document their Quality System in a Quality Management Plan (QMP), formerly called a Quality Assurance Program Plan (QAPgP). Region 6 EPA policy requires submission of Quality Management Plans prior to any approval for EPA funding. Quality Systems encompass the management and technical activities necessary to plan, implement, and assess the effectiveness of quality assurance (QA) and quality control (QC) operations applied to environmental programs. This plan provides the blueprint for how an individual organization or organizational component will plan, implement, and assess its Quality System for the environmental work to be performed as part of its mission.

Approval of a QMP by the accountable official for the organizational unit preparing the plan and by the senior management official at the next higher level in the organization is required prior to submission. Any QMP received without the required approval signatures will be returned without being reviewed. The EPA Region 6 Quality Assurance Team will review the QMP and, if fully compliant with all Agency and Regional QA requirements listed in this document, approve it. Final approval of a QMP for Region 6 is made by the Region 6 Quality Assurance Manager.

Contractors that perform work for or on behalf of EPA must provide a QMP as evidence of their own established Quality System. Such QMPs are submitted, reviewed and approved by the same process as described in the paragraph above, as part of the contract procurement. The process used by grantees and contractors to review and approve QMPs from outside their own organizational units, whether by contract or sub-contract, agreement or sub-agreement, must be described in their organization's QMP.

The QMP is management's statement of the process governing the QA/QC activities for a given organization. That is, the QMP describes how the organization will conduct its business.

The QMP defines an organization's QA-related:

- policies,
- criteria for and areas of application, and,
- definition of roles, responsibilities, and authorities.

The QMP, therefore, is a management tool that should be appropriately tailored to the needs of its organization and that defines how its quality management objectives will be attained. The QMP must be sufficiently inclusive and explicit to allow subordinate managers and supervisors to understand the priority which management places on QA, the established QA policies and procedures, and their respective QA roles. The QMP must be so constructed and so written that an assessment of its implementation should be able to determine whether or not the Quality System is being managed in a way that guarantees successful environmental programs. In practice, the QMP should be focused on the processes used to plan, implement, and assess the programs to which it is applied. The level of detail should be based on a graded approach[1] that establishes QA and QC requirements commensurate with the importance of the work and the unique needs of the organization.

The specifications presented in this Chapter are based on principles of organizational flexibility so that the plan can be tailored to individual requirements and modified as the requirements change. This document describes the key QA management elements which are normally considered to be important in a quality system. Some elements are mandatory to ensure consistency across EPA Region 6 Grantee/Contractor Quality Systems. Other elements may be mission-specific and may not apply to every organization. Each organization should evaluate these key elements to see if they are applicable to their quality system. Where a particular element is not relevant, a brief explanation of why it is not relevant should be provided in the quality management document. On the other hand, if additional quality management elements are deemed useful or necessary for an adequate Quality System, that group is encouraged to develop these elements and discuss them in their Quality System documents.

Quality Management Plan Preparation, Submission, Review, and Approval

QMP Preparation Responsibility

Each senior manager is responsible for the preparation of a QMP to cover all environmental programs for which the manager is accountable. The term *senior manager* refers to managers who are responsible and accountable for mission accomplishment and overall operations. The term *management or line management* refers to those individuals directly responsible and accountable for

[1] A graded approach to QA/QC bases the level of managerial controls on the intended use of the results and the degree of confidence needed in the quality of the results.

planning, implementing, and assessing environmental programs. Several levels of senior management may exist and may include, but are not limited to, Office Directors, Laboratory Directors, Division Directors, and Bureau Chiefs. "Environmental data" include all field and laboratory measurements of chemical, physical, and biological parameters in or pertaining to the environment as established by the definition in Chapter 1. Senior management is responsible for ensuring that the Quality System documented in the QMP meets all compliance requirements with this Quality Manual.

While senior management is responsible for the preparation of the QMP, the physical preparation may be assigned to the organization's staff so long as it is assured that all line managers participate in and support the effort. It is essential that line management understand fully the content of the QMP and concur with its implementation. It is recommended and highly desirable that this concurrence be documented by line managers signatures as "Concurring Officials" on the approvals page of the QMP. The preparation of the QMP may be directed by the Quality Assurance Manager (QAM).

Drafts of a QMP are not acceptable, due to resource constraints on the Region 6 Quality Assurance Team. Assistance will be provided and questions answered by the Region 6 Quality Assurance Team staff to support the writing and reviewing process. Call (214) 665-2217 to receive such assistance.

The Region 6 Quality Assurance Team has committed to a 15 working day turnaround time for reviewing QMPs. This is a goal we strive to meet, as we recognize the need to provide prompt feedback to our customers.

Internal Approval and Submission

The QMP must be approved by the accountable manager of the organization preparing the QMP. This will certify that the organization has conducted an internal review of the QMP and that line management has concurred with its contents and supports its implementation. The senior manager should indicate his/her approval of the QMP on the signature page of the document. The senior manager may require the concurrence of appropriate subordinate line managers on the QA documentation if he/she believes this to be beneficial to the group's Quality System. It is recommended that three sets of approval/concurrence pages be submitted, all with original signatures.

Region 6 QA Office Review and Approval of the QMP

Following the internal review and approval, the QMP must be submitted to EPA Region 6 for review for compliance with EPA Quality System requirements. Within 15 days of receipt of a QMP (Received in the QA Office), the QA Office will either approve or disapprove and provide

detailed comments and suggestions for improving the QMP so that it can be revised and approved upon resubmission. An approval by Region 6 Quality Assurance Team is valid for a period not to exceed one year. Each year after the initial approval of a QMP a revision and update of the QMP is required. Many organizations make changes to their internal processes which need to be documented. Personnel change over time through promotion, attrition and reassignment, and these changes require documentation.

In its reviews of QMPs, the QA Office staff focuses on the substance of the organization's QA management process and not on format or technical details. QA Office staff will recommend approval for those QMPs it believes reflect acceptable QA policies,procedures, administrative criteria, and management systems for key QA elements including Data Quality Objectives, QA Project Plans, other QMPs (from organizations that are involved by contract, agreement or sub-contract, sub-agreement), Standard Operating Procedures, assessments, and oversight of delegated programs. QA Office staff will review the QMPs for compliance with current Regional and National EPA Quality System requirements and the inclusion of all mandatory program elements.

QMP Revisions

Region 6 and National EPA policy requires that all Quality Systems be reviewed at least annually by their organizations to assure the effectiveness of the quality management practices described in the QMP. This assessment must also include an evaluation of the effectiveness of the QMP. The process of developing and annually updating the QMP provides an opportunity for management and staff to clarify roles and responsibilities, address problem areas, and acknowledge successes so that they may be fostered and rewarded. Having an accurate QMP at all times is an essential element in every Quality System. Changes in QA policy and procedures should be documented in a timely fashion by QMP revisions. In general, a copy of any QMP revision(s) made during the year should be submitted as an attachment to or as part of the QA Annual Report and Work Plan (QAARWP) if required as a grant condition, contract deliverable or the QMP of the organization. In some cases, however, it may be necessary to re-submit the entire QMP if significant changes have been made to the Quality System. If the entire QMP is current, valid and accurately reflects the organization's policy, **at a minimum**, each year the organization will submit to EPA Region 6 a certification that the plan is current, to include a copy of new, signed approval pages for the QMP.

It is management's responsibility to assure that all changes to the Quality System and the QMP are distributed to all personnel performing work for the organization, including active contractors, sub-contractors, and agreement, and sub-agreement parties.

Quality Management Plan Requirements

General Requirements

The QMP is the blueprint for an organization's quality management process in support of technical operations. That is, the QMP documents the entire framework and structure for the QA/QC processes used by the organization. In general, the QMP should describe how the organization plans and implements the necessary quality management practices, including QA/QC, to ensure that the results of its technical work are of the type and quality needed for their intended use. Accordingly, the QMP will contain discussions of such subjects as:

- the quality policy and mission of the organization,
- the specific roles and responsibilities of top management and employees for required QA/QC activities,
- the structure for effective communications,
- how measures of effectiveness will be established and how frequently effectiveness will be measured, and
- how continual improvement will occur.

The QMP reflects the organization's commitment to quality management principles and practices, tailored by senior management to meet the organization's needs. A Quality Management Plan, minimally, must address the topics addressed in subsequent sections of this document. It is preferable, but not necessary, that the QMP cover the topics in the same order as presented below. If an existing QMP adequately addresses each of these topics, but in a different order, it should not be rewritten simply to conform to the outline provided here. The important element here is content, not format. A discussion is provided under each topic heading to clarify the type of information that is expected to be presented in a QMP.

Because the nature of the Quality System will vary among organizations, the content and organization of QMPs will also vary. In general, the QMP should address all of the components of the Quality System and discuss HOW they should be carried out and by WHOM.

The following Quality System elements include the subjects listed above as well as others and must be addressed by the QMP:

- Management and Organization,
- Quality System and Description,
- Personnel Qualification and Training
- Procurement of Items and Services,
- Documentation and Records,
- Computer Hardware and Software,
- Planning,
- Implementation of Work Processes,
- Assessment and Response, and
- Quality Improvement.

If an organization believes that an element or a sub-element is not applicable to its Quality System, then it must state why this is the case. In the discussions to follow, specific requirements are presented on what should be addressed or included within each of these program elements.

1 Management and Organization

Specific Requirements:

This section of the QMP shall contain or address the following management and organizational items:

- a statement of the organization's policy on quality assurance, including:
  - the level of importance of QA/QC to the organization and why,
  - the general objectives/goals for QA/QC, and
  - the commitment of resources for QA/QC;
- an organization chart that identifies all of the components of the organization and, in particular, the organizational position of the QA Manager/QA Officer;
- a discussion of the responsibilities and authorities of the QA Manager/QA Officer and any other QA staff, including:
  - the line of reporting to senior management, and
  - the means by which management will be kept informed about quality issues;
- a discussion of the mission of each organization component, functional responsibilities of management and staff, levels of accountability and authority, and

lines of communication for planning, implementing, and assessing environmental programs;

- a discussion of the QA/QC roles and responsibilities of line management, technical staff, and any other staff;
- identification of all activities to which QA/QC are to be applied;
- how management will assure that applicable elements of the Quality System are understood and are implemented in all activities under their responsibility involving environmental programs;
- an approval page for the signatures of the accountable managers, senior line management (as appropriate), and the QA Manager/QA Officer of the organization, and for the Region 6 QA Officer, and appropriate Region 6 Program Office staff. This approval page may be part of a title page or a separate sheet following the title page.

Rationale:

The QMP represents an opportunity for the organization's accountable managers to inform subordinates of the priority accorded to QA/QC and the reasons for that priority. The QMP also represents an opportunity to document important broad quality policies such as the need to incorporate QA in the up-front planning of activities entailing environmental data collection and the need for personal involvement of subordinate managers and supervisors in day-today QA/QC activities.

It is appropriate to begin the QMP with a statement of the organization's policy on quality assurance. It should convey senior management's views on the level of importance and priority that the organization's personnel should give to quality assurance in environmental sampling and analysis activities conducted by, or in support of the organization. Recognition and support for senior management's policies should be affirmed by subordinate managers by their inclusion as concurring officials on the approval page. An explanation of why QA should be afforded the indicated level of importance and priority is also appropriate. The QMP should contain a statement of the general objective/goals that the organization intends to achieve through its Quality System. This statement may be combined with the Policy Statement described above. A commitment to assuring the availability of the time and resources needed to obtain the type and quality of program results needed to satisfy mission objectives should be included. The policy statement should emphasize those requirements and activities needed to assure data quality. The *specific* policies and procedures addressed elsewhere in the QMP need not be repeated here. The basic objective of an organization's Quality System is to provide a process for management's review and oversight at the planning, implementation, and assessment stages of environmental programs.

2 Quality System and Description

Specific Requirements:

This section of the QMP shall contain or address the following items pertaining to the Quality System and the technical mission to which it applies:

? A discussion of the principal components or "tools" comprising the organization's Quality System and the process and procedures for their use. These components include, but are not limited to:

- Quality Management Plans
- Management Systems Reviews
- Data Quality Objectives Process
- QA Project Plans
- Standard Operating Procedures
- Technical Assessments (Self and Independent)
- Data Quality Assessments

The process discussion should include the roles and responsibilities for all management and staff in planning and implementing the Quality System.

? A discussion of the technical activities or programs that are supported by the Quality System and to which the QA/QC controls apply; that is, the specific programs that require extensive QA/QC controls; where oversight of delegated, contracted, or other extramural programs is needed to assure data quality; and, where internal coordination of QA/QC among the group's organizational units need to occur.

Rationale:

The QMP should describe the Quality System process used by the organization to plan, implement, and assess the effectiveness of QA/QC activities applied to its environmental programs. Such a process description should include how key QA/QC functions are to be performed, what "tools" or procedures are used, and who is responsible for doing the work.

The QMP should identify the programmatic activities of the associated organizations covered by the Quality System and describe its structure, policies and procedures, functional responsibilities, levels of accountability and authority, and necessary interfaces. By identifying and describing these activities (i.e., projects, tasks, etc.), the organization specifies the necessary foundation for defining and stipulating the items that are essential to planning an effective Quality System. The QMP should identify and briefly describe each significant program undertaken or supported by the group. Pertinent information might include the nature and size of each program

and the administrative vehicle by which they are implemented; i.e., by the efforts of internal organizational employees, by contract, by cooperative agreement, by grant, or by delegation of responsibility through a inter-agency agreement to or from state government agencies.

The QMP should define and document *how and when* QA/QC activities applied to individual projects and tasks at the technical/project level are planned, implemented, and assessed. The QMP is the formal means by which management documents how QA/QC will be applied to environmental programs; that is, it provides the "blueprint" for how the Quality System will operate. Moreover, the QMP provides the basis or criteria for assessing the effectiveness of the Quality System.

3 Personnel Qualifications and Training

Specific Requirements:

The QMP must reflect management's commitment to and describe its systems for:

- identifying certifications required to perform operations for the different programs for which the organization is responsible;
- establishing training requirements for personnel;
- identifying and satisfying technical and project management training needs;
- identifying and/or designing training programs to meet these needs;
- performing introductory training and continuing training (or re-training);
- encouraging professional development beyond initial qualifications;
- documenting and maintaining training records for personnel;
- identifying qualified trainers;
- assessing the effectiveness of training and (where applicable) establishing a program for training and updating the instructors on training techniques and technical changes; and
- reviewing and updating training materials and course content.

Included in the above is the responsibility of management to identify what qualifications or certifications are necessary for personnel to perform their work safely and effectively.

Rationale:

As stated earlier, EPA policy requires that personnel performing work on environmental programs shall be qualified to perform assigned work, including and according to any project-specific requirements. The QMP should include a description of the organization's process for identifying and satisfying training needs on a continuing basis. Accordingly, this section shall describe the organization's process for establishing training requirements, identifying training needs, assigning priorities to them, and satisfying them in priority order.

The training categories must be specified in the QMP or reference must be made to the organization's formalized training program. The following are examples of possible training categories associated with environmental programs:

- fundamental principles of quality;
- the organization's QA policies and procedures;
- technical skills (e.g., statistics, experimental design);
- management and communication skills; and
- specialized topics (e.g., risk management).

The selection of mandatory and optional topics within training categories should be based on the results of a systematic evaluation of the organization's needs. In addition to classroom-style training, the organization should consider taking advantage of on-the-job training as well as innovative techniques such as computer-based training.

Management should evaluate each position to determine what qualifications are necessary for personnel to execute their quality-related responsibilities in a safe and effective manner. These qualifications must be documented in terms of education, experience, training, technical knowledge, or combinations of the above. Qualifications should reflect the hazard and risk associated with a specific position; when appropriate, qualifications based on hazard and risk should be established for individual projects, and required of personnel for the duration of the project.

4 Procurement of Items and Services

Specific Requirements:

This section of the QMP shall contain discussions of or address the following issues pertaining to the procurement of items and services:

- the organization's process for assuring that QA/QC requirements are defined for all applicable acquisitions and that this assurance process is documented for each

acquisition action;

- how changes to procurement documents will receive the same review approvals as the original documents;

- the organization's process for assuring that QA/QC requirements are adequately addressed in all responses to applicable solicitations and that QA/QC is an integral criterion of the evaluation criteria; and

- the organization's process for ensuring that contracted and subcontracted activities produce results of acceptable quality, including, as appropriate: procurement source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspections, supplier audits, and examination of deliverables.

Rationale:

The procurement process must ensure that approved suppliers continue to provide acceptable items and services. Procurement documents or financial assistance agreements shall require suppliers (i.e., contractors, subcontractors, or financial assistance recipients) to have a Quality System consistent with EPA QA requirements. *This requirement applies only to those suppliers who provide services or items that directly affect the quality of results or products from environmental programs*. The management system should describe: the pre-award planning of procurement needs and activities; the identification, documentation, review, and approval of technical specifications; the selection and documentation of evaluation criteria and necessary certifications; the qualification and approval process of contractors and subcontractors; the evaluation of contractor and subcontractor QMPs to ensure compliance with the guidelines presented in this requirements document; the identification of procedures for review and approval of negotiations, compromises or changes regarding technical issues; documentation of the procurement process; and the evaluation and verification of post-award quality versus original pre-award acceptance criteria.

The EPA recognizes the concept of *privity of the contract* that applies between a prime and a sub-contractor, and in theory, follows that concept in application to grants, cooperative agreements and interagency agreements. The EPA looks to the organization that was awarded a grant, contract or interagency agreement to accept full responsibility for quality of all work performed under that specific grant, contract or interagency agreement, regardless of whether or not that organization actually performed the work or by some means had the work performed by another entity. Each supplier/customer relationship requires each customer to be responsible for fully and specifically informing a supplier of all quality expectations, and assuring that all items and services provided by their subcontractors and suppliers meet those expectations. How this occurs, and the process that assures it is of acceptable quality must be delineated in this section of the QMP.

5 Documents and Records

Specific Requirements:

This section of the QMP must include:

- a description of the organization's process for identifying quality-related documents and records requiring control;
- a description of the organization's process for handling documents and records to assure their accessibility, protection from damage and deterioration, and means of retention, including discussion of the roles and responsibilities for management and staff;
- a description of the process by which all technical guidance documents are prepared, reviewed, approved, issued, used, and revised; and
- a description of the process that ensures compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs and that provides adequate preservation of key records necessary to support the mission of the organization.

Rationale:

Organizations that perform environmental sampling, analysis, and project management activities must establish and maintain procedures for the timely preparation, review, approval, issuance, use, control, revision and maintenance of documents and records. For the purposes of these requirements, a document is any volume that contains information which describes, defines, specifies, reports, certifies, requires, or provides data or results pertaining to environmental programs. A record is a completed document that provides objective evidence of an item or process. A document which contains objective information can become a record once it is complete and identified as a record.

The QMP must define and establish a management process that controls preparation, review, approval, issuance, use, and revision of all technical guidance documents, especially planning documents; i.e., QA Project Plans, Sampling and Analysis Plans, and Standard Operating Procedures (SOPs). Such documents, including revisions, must be reviewed for conformance with the Quality System requirements and approved by authorized personnel for general use. To facilitate the use of documents, consistency in formats shall be encouraged for similar types of documents, such as standard operating procedures (SOPs).

The QMP must also define a management process for records to ensure that they accurately

reflect completed work and/or fulfill statutory and EPA requirements. The maintenance of records should include requirements and responsibilities for record transmittal, distribution, retention, protection, preservation, traceability, disposition, and retrievability. To facilitate their accessibility and use, records must comply with required formats such as that required for analytical data by Good Automated Laboratory Practices (GALP) (Ref. 5). The QMP should also identify how the disposition of records, in accordance with regulatory requirements, schedules, or directives from senior management, is accomplished.

6 Computer Hardware and Software

Specific Requirements:

This section of the QMP shall address the use of computer hardware and software in the organization's operations. Specifically, the QMP must:

- describe the process for ensuring that computer hardware used in environmental programs meets the requirements of these programs;
- describe how changes to hardware shall be controlled to assess the impact of the change on performance;
- describe the process for developing computer software, for validating, verifying, and documenting the software for its use, and for assuring that the software meets the requirements of the user;
- describe how purchased software is evaluated to meet user requirements and to comply with applicable organizational policy regarding software proliferation and configuration management standards; and
- describe the process for ensuring that data and information produced from or collected by computers meet applicable organizational policy standards.

These descriptions shall include the roles and responsibilities assigned to management and staff.

Rationale:

There is increasing dependence on computer hardware and software to support environmental programs in a variety of ways. Computer hardware must be appropriate for its intended application. Computer programs used in environmental data operations and for environmental technology design, construction, and operation should be developed using software development methodology approved by authorized personnel. Computer programs covered by this policy include but are not limited to design, design analysis, modeling of environmental processes

and conditions, operations or process control, and data bases or document control registers (when used as the controlled source of quality information). The QMP should document how the organization manages its computer hardware and software operations that directly impact the quality of the results of environmental programs.

7 Planning

Specific Requirements:

This section of the QMP shall document how and by whom work shall be planned by the organization. Minimally, the QMP shall describe the system or process used to:

- identify the customer for whom the work is to be performed,
- identify the needs and expectations of the customer in terms of both technical and quality goals,
- translate the customer's needs into specifications to produce the desired result,
- consider any cost and schedule constraints within which project activities are required to be performed, and
- identify acceptance criteria for the result or measures of performance by which customer satisfaction will be determined.

All projects involving the generation, acquisition and use of environmental data shall be planned using a systematic planning process such as the Data Quality Objective process as defined by the current revision of Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process, EPA QA/G-4, or acceptable alternate, and shall be documented in a Quality Assurance Project Plan (QAPP), as defined by the current revision of EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5, and approved by authorized QA personnel for implementation.

Rationale:

The planning process should ensure that all organizations and/or parties who contribute to the quality of the environmental program results are identified and that they participate in the planning process. The planning process should include direct communication between the customer and the supplier to ensure that there is a clear understanding by all participants of the needs and expectations of the customer and the product or results to be provided by the supplier. How this occurs and is documented must be specifically addressed in the QMP.

Management should ensure that the unique planning requirements for different environmental programs, projects or tasks are addressed and documented according to the needs of the specific work to be performed. Such documentation may be in the form of work plans, schedules, and QAPPs.

The QMP should describe the interface between the Quality System and the technical activities conducted by the organization. The following issues pertain to all such activities and should be addressed by the QMP.

- Communication - The collection of environmental data is often a complicated process whose success is dependent upon the correct sequence and execution of a number of related steps and details by personnel having different areas of expertise. The QMP should describe the system of communications to ensure that all personnel are aware of their roles and responsibilities in the overall project before project initiation. Communications should continue during project implementation so that complications and necessary deviations can be addressed in a timely manner.

- Documentation - Documentation is necessary to implement and validate sampling and analytical efforts, to detect problems, and to explain unexpected phenomena. Implementation of the work process will rely upon the documentation included in the QAPP as well as details documented in SOPs referenced by the Plan. The QMP should describe in general what organizational and project information is be documented and how this information will be distributed, reviewed, and archived.

- Health & Safety - The QMP must emphasize the overriding importance of health and safety issues, and document mechanisms for review of all organizational and project activities for compliance with existing organizational health and safety requirements or for their potential impact on the health and safety of personnel, prior to the initiation of activities.

The QMP should describe how all work is accomplished in the proper sequence and in accordance with approved planning documentation. All environmental programs do not require the same degree of quality control. QMPs should define how to establish the needed level of quality control. QMPs define how to establish the needed level of quality control by selecting data quality requirements using the Data Quality Objectives (DQO) process or similar technique.

8 Implementation of Work Processes

Specific Requirements:

This section of the QMP shall describe the process of how and by whom work shall be implemented by or on behalf of the organization. Minimally, the QMP must describe:

? the procedures for ensuring that work is performed according to plan;

? the needed level of management oversight and inspection that will be commensurate with the importance of the particular project and the intended use of the project results; and

? how procedures for appropriate routine, standardized, special, or critical operations are developed and implemented, including the policies and procedures that address, but are not limited to:

- identification of operations needing procedures;
- preparation of procedures, including form, content, and applicability; and
- review and approval of procedures.

The QMP must stress that environmental data operations project will be implemented in accordance with the Quality Assurance Project Plan. The QMP shall consider those activities, policies, and procedures that are common to all projects of the specific organization. It must also emphasize the importance of documenting activities including any exceptions to the QA Project Plan.

The organization shall describe how appropriate measures for controlling the release, change, and use of planned procedures are implemented. These measures shall provide for the necessary approvals, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as prescribed.

Rationale:

Line managers are responsible for implementing the approved QAPP and the QMP. This includes organizing and planning activities to meet quality requirements consistently; coordinating work performance for specific projects; and training and qualifying personnel to achieve and maintain proficiency. The mechanism for implementing these responsibilities should be described in the QMP.

The QMP should describe how satisfactory performance will be determined from established technical and quality specifications. The work process should be monitored to ensure continued satisfactory performance. The independence of personnel monitoring work performance should be demonstrated and be commensurate with the nature and importance of the activity. Inspection, use of analytical QC samples, and non-destructive testing (NDT) are examples of measurement of work performance.

Standard operating procedures (SOPs) are encouraged for appropriate routine, standardized, or special/critical operations. If SOPs are to be utilized by the organization, and referenced in the

QMP or a QAPP for a specific project then the QMP should contain policies and procedures for identifying and addressing SOPs. The QMP should also describe the process by which SOPs shall be reviewed for adequacy by technically qualified personnel before use.

9 Assessment and Response

Specific Requirements:

Assessments are evaluations intended to increase the user's understanding of the program or system being assessed, and to provide a basis for improving such programs or systems. This section of the QMP must describe how and by whom assessments of environmental programs are planned, conducted, and evaluated to measure the effectiveness of the implemented quality system. This section of the QMP shall also describe how management determines during planning which type of assessment activity is appropriate for a particular project and which assessment tool is to be used. The assessment tools for environmental programs encompass:

- management systems reviews,
- surveillances,
- audits,
- performance evaluations,
- audits of data quality,
- peer reviews and technical reviews,
- readiness reviews, and
- data quality assessments.

This section shall contain or address the following items pertaining to management assessment of the effectiveness of the organization's Quality System:

- how the process for the planning, scheduling, and implementation of assessments works, as well as how the organization will respond to needed changes;

- definition of responsibilities, levels of participation, and authorities for all management and staff for the assessment process; and

- discussion of how, when, and by whom actions will be taken in response to the findings of the assessment, and how the effectiveness of the response will be determined. Personnel conducting assessments shall be qualified based on project-specific requirements to perform the assigned assessment. The QMP must describe how the level of competence, experience, and training necessary to ensure the capability of personnel conducting assessments is determined. The QMP must document how persons conducting assessments must have sufficient authority, access to programs and managers, access to documents and records, and organiza-

tional freedom to:

- identify quality problems;
- identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products;
- propose recommendations for resolving quality problems;
- independently confirm implementation and effectiveness of solutions; and
- provide documented assurance to line management that, when problems are identified, further work performed is monitored carefully until the problems are suitably resolved.

The QMP must clearly define the responsibilities and authorities of personnel conducting assessments, particularly in regard to authority to suspend or stop work in progress upon detection and identification of an immediate adverse condition affecting the quality of results or the health and safety of personnel.

The QMP must describe how management will respond to the findings and recommendations from assessments in a timely manner. When conditions needing corrective action are identified, the appropriate response must be made promptly. The QMP should indicate how follow-up action shall be taken and documented to confirm the implementation and effectiveness of the response action.

Environmental data must be qualified according to the intended use of the data. Data obtained from sources that did not use, or fully comply with, a QA Project Plan (or equivalent planning document) for data collection must also be qualified. Data shall be qualified according to procedures documented in the QMP. These procedures shall document the decision process and factors used in arriving at the choice of the particular qualification method. This process shall include the correct application of statistical methods during the assessment process. The decision to qualify the data for their intended use shall be based on reconciliation with the performance measures for the project defined by the data quality requirements. Any limitations on data use shall be identified quantitatively to the extent practicable and fully documented.

The QMP shall also describe how project reports containing data or reporting the results of environmental data operations shall be reviewed independently to confirm that the data or results are presented correctly. The QMP shall describe the process used for these reviews and the approval authority required prior to the publication or distribution of any reports.

The QMP shall also describe the process by which periodic assessments of environmental programs are planned, scheduled and implemented. Line management is responsible for overseeing assessments and for responding to their findings. Scheduling of assessments and allocation of resources are to be based on the status, risk and complexity of the sampling and analytical activities.

Rationale:

Assessments should include an evaluation to determine whether technical requirements, not just procedural compliance, are being met effectively. Assessments should be performed according to approved written procedures from management, based on careful planning of scope of the assessment and the information needed. The QMP should describe how assessment results shall be documented, reported to, and reviewed by management.

The type of assessment is determined by management. Four general types of assessments are described below:

- **management self-assessment**: the qualitative assessment of a particular program operation and/or organization(s) *by those immediately responsible for overseeing and/or performing the work* to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of results needed are obtained.

- **management independent assessment**: the qualitative assessment of a particular program operation and/or organization(s) *by someone other than the group performing the work* to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of results needed are obtained.

- **technical self-assessment**: the evaluation process used *by those immediately responsible for overseeing and/or performing the work* to measure the performance or effectiveness of a technical system and its elements with respect to documented specifications and objectives. Such assessments may include qualitative and quantitative evaluations.

- **technical independent assessment**: the evaluation process used *by someone other than the group performing the work* to measure the performance or effectiveness of a technical system and its elements with respect to documented specifications and objectives. Such assessments may involve qualitative and quantitative evaluations, and may include peer reviews and audits.

Management is responsible for choosing the assessors, defining acceptance criteria, approving audit check lists, and identifying goals prior to initiation of an assessment. Assessors are

technically knowledgeable people with no real or perceived conflict of interest. If the assessors are chosen from within the organization, they must have no involvement or responsibility for the work being assessed. Personnel conducting independent assessments should be qualified, certified when necessary, and have sufficient authority to conduct the assessment activities. The QMP should detail how the assessors are selected and how the limits of their authority will be determined.

Senior management is required to regularly assess (at least annually) and document the adequacy of the framework and infrastructure of the Quality System for which they are responsible and to ensure its effective implementation. The organization's approved QMP provides the primary criteria for these assessments. Such assessments shall provide a means for determining and taking necessary response actions regarding:

- Effectiveness of the system of management controls that are established to achieve and assure quality, and

- Adequacy of resources and personnel provided to achieve quality objectives in all activities to which the Quality System applies.

These planned and periodic management assessments, or Management Systems Reviews (MSRs), are to be established and implemented according to procedures detailed in the QMP. Management assessments focus on how well the integrated Quality System is working, and identify and correct management barriers that hinder the organization from achieving its objectives. Management assessments address the effectiveness of management controls to achieve and assure quality, the adequacy of resources and personnel, the effectiveness of training and assessments, and applicability of data quality requirements and software. Management assessments consider both noteworthy accomplishments and significant QA problems, and identify opportunities for improvement.

10 Quality Improvement

Specific Requirements:

This section of the QMP shall include a description of the organization's management system for detecting and preventing quality problems and for ensuring continuing quality improvement. Accordingly, this section shall describe:

- the management process and identify who (organizationally) is responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities;

- a corrective action program to ensure that conditions adverse to quality are identified promptly and corrected as soon as practical. Corrective actions shall include the

identification of root causes of problems, determining if the problem is unique or has more generic implications, and recommending procedures to prevent recurrence.

Rationale:

The process of continuous quality improvement leads to the development of a better and more responsive quality system. Quality problems are often inherent in existing management and technical systems, and workers may have little or no control over eliminating these problems or improving performance. Lessons learned from assessments and from operating experiences may be used to augment or enhance an organization's systems and technical operations. In environmental programs, quality improvement results from processes that:

? prevent or minimize problems (during planning, sampling, analysis, project management, and data handling) that may affect the quality of environmental data;

? detect and correct these problems when they do occur; and

? review existing performance and identify opportunities for qualify improvement.

The QMP should describe how the use of the following program elements will help to prevent the occurrence of problems that can affect the quality of environmental data:

? SOPs,
? personnel training,
? QC samples, checks, and inspections,
? documentation of implementation activities,
? documentation of personnel responsible for sampling and analytical activities.

However, specific planning, sampling, analytical, and program management activities that do not meet established requirements (i.e., deficiencies, nonconformances) should be identified, controlled, documented, reported, and corrected.

The QMP should describe how staff at all levels are encouraged to identify customers and suppliers, identify process improvement opportunities, identify problems, and offer solutions to those problems. Motivation of staff begins with their understanding of the tasks they are expected to perform and how those tasks support the overall mission of the organization. The QMP should identify how employees are made aware of the advantages of proper job performance at all levels and of the effects of poor job performance on other employees, customer satisfaction, and costs. The QMP should show how management encourages continuous quality improvement and encourages staff and other managers to exceed the expectations of their customers whenever possible as a quality improvement goal.

APPENDIX A

TERMS AND DEFINITION

Activity - an all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.

Assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. In this Standard, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection or surveillance.

Audit - a planned and documented investigative evaluation of an item or process to determine the adequacy and effectiveness as well as compliance with established procedures, instructions, drawings, QAPPs, and other applicable documents.

Characteristic - any property or attribute of a datum, item, process, or service that is distinct, describable, and measurable.

Computer Program - a sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution. A computer program may be stored on magnetic media, and be referred to as "software", or may be stored permanently on computer chips, and be referred to as "firmware". Computer programs covered by this Standard are those used for design analysis, data acquisition, data reduction, data storage (data bases), operation or control, and data base or document control registers when used as the controlled source of quality information.

Contractor - any organization or individual that contracts to furnish services or items or perform work.

Corrective Action - measures taken to rectify conditions adverse to quality and, where necessary, to preclude their recurrence.

Customer - any individual or organization for whom items or services are furnished or work performed in response to defined requirements and expectations.

Data Quality Assessment (DQA) - a **process** of statistical and scientific evaluation that is used to assess the validity and performance of the data collection design and statistical test, and to establish whether a data set is adequate for its intended use.

Data Quality Objectives (DQOs) - a statement of the precise data, the manner in which such data may be combined, and the acceptable uncertainty in those data in order to resolve an environmental problem or condition. This may also include the criteria or specifications needed to design a study that resolves the question or decision addressed by the **DQO process**.

Data Quality Objectives Process - a Total Quality Management (TQM) tool, based on the Scientific Method and developed by the U.S. Environmental Protection Agency to facilitate the planning of environmental data collection activities. The DQO process enables planners to focus their planning efforts by specifying the use of the data (the decision), the decision criteria (action level), and the decision maker's acceptable decision error rates. The products of the DQO process are the DQOs (See also **Graded Approach**).

Data Usability - the process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

Design Review - a documented evaluation by a team, including personnel other than the original designers, the responsible designers, the customer for the work or product being designed, and a QA representative to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

Engineered Environmental Systems - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollutant reduction or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Environmental Conditions - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

Environmental Data - any measurements or information that describe environmental processes or conditions, or the performance of engineered environmental systems.

Environmental Data Operations - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

Environmental Monitoring - the process of measuring or collecting environmental data.

Environmental Processes - manufactured or natural processes that produce discharges to or impact the ambient environment.

Environmental Programs - an all-inclusive term pertaining to any work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of engineered environmental systems; and laboratory operations on environmental samples.

Environmentally Related Measurements - the data collection activity or investigation involving the assessment of chemical, physical or biological factors in the environment which affect human health or the quality of life.

Financial Assistance - the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and government interagency agreements.

Graded Approach - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of results and the degree of confidence needed in the quality of the results. (See **Data Quality Objectives Process**).

Hazardous Waste - any waste materials that satisfies the definition of "hazardous waste" as given in 40 CFR Part 261, "Identification and Listing of Hazardous Waste".

Independent Assessment - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

Inspection - examination or measurement of an item or activity to verify conformance to specific requirements.

Item - an all-inclusive term used in place of the following: appurtenance, facility, sample assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts, or data.

Management - those individuals directly responsible and accountable for planning, implementing, and assessing work.

Management System - a structured non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management System Review (MSR) - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies,

practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

May - denotes permission but not a requirement.

Method - a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

Mixed Waste - hazardous waste material, as defined by 40 CFR part 261 (RCRA), mixed with radioactive constituents.

Must - denotes a requirement that has to be met.

Peer Review - a documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. The peer review is conducted by qualified individuals (or organization) who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. The peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

Performance Evaluation (PE) - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Procedure - a documented set of steps or actions that systematically specifies or describes how an activity is to be performed.

Process - an orderly system of actions that are intended to achieve a desired end or result. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

QTRAK - is a **Computer Program** that contains database information on Quality Management Plans and Quality Assurance Project Plans to the Program Managers, Project Officers, and the OQA for planning and assessment of the status of regional Quality Management Plans and the associated Project Plans.

Qualified Data - any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations.

Quality - the sum of features and properties/characteristics of a process, item, or service that bears on its ability to meet the stated needs and expectations of the user.

Quality Assurance (QA) - an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer.

Quality Assurance Management Staff (QAMS) - the U.S. EPA's headquarters staff element that establishes and promulgates Quality Assurance Policy.

Quality Assurance Officer (QAO) - the designated Region 6 staff member that has the delegated authority for approval of all Quality Management Plans in Region 6, Chief of the Office of Quality Assurance.

Quality Assurance Program Description/Plan -see **Quality Management Plan**.

Quality Assurance Project Plan (QAPP) - a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

Quality Control (QC) - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer.

Quality Improvement - a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

Quality Indicators - measurable attributes of the attainment of the necessary quality for a particular environmental decision. Indicators of quality include precision, bias, completeness, representativeness, reproducibility, comparability, and statistical confidence.

Quality Management - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

Quality Management Plan (QMP) - a formal document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

Quality System - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

Radioactive Waste - waste material containing radionuclides, or contaminated by radionuclides.

Readiness Review - a systematic, documented review of the readiness for the startup or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

Remediation - the process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health.

Research (Applied) - a process, the objective of which is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

Research (Basic) - a process, the objective of which is to gain knowledge or understanding of the fundamental aspect of phenomena and of observable facts without specific applications toward processes or products in mind.

Research Development/Demonstration - Systematic use of the knowledge and understanding gained from research and directed toward the production of useful materials, devices, systems, or methods, including prototypes and processes.

Self-Assessment - Assessments of work conducting by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

Service - the category of economic activity that does not produce manufactured items. In environmental data operations or engineering projects, such activities include design, inspection, laboratory and/or field analysis, repair, and installation.

Shall - denotes a requirement that is mandatory and has to be met.

Should - denotes a guideline or recommendation.

Significant Condition - any state, status, incident, or situation of an environmental process or condition of an engineered environmental system in which the work being performed will be adversely affected in a manner sufficiently serious to require corrective action to satisfy quality objectives or specifications and safety requirements.

Software Life Cycle - the period of time that starts when a software product is conceived and ends

when the software product is no longer available for routine use. The software life cycle typically includes a requirements phase, a design phase, an implementation phase, a test phase, an installation and check-out phase, an operation and maintenance phase, and sometimes a retirement phase.

Standard Operating Procedure (SOP) - a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is Officially approved as the method for performing certain routine or repetitive tasks.

Supplier - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

Surveillance - the act of monitoring or observing a process or activity to verify conformance to specified requirements.

Technical Review - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The reviews are an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

Technical Systems Audit (TSA) - a thorough, systematic, on-site qualitative audit of facilities, equipment, personnel, training procedures, record keeping, data validation, data management, and reporting aspects of a system.

Total Quality Management (TQM) - the process of applying quality management to all activities of the organization, including technical and administrative operations. See Quality Management and Quality System.

Validation - an activity that demonstrates or confirms that a process, item, data set, or service satisfies the requirements defined by the user.

Verification - the act of authenticating or formally asserting the truth that a process, item, data set, or service is, in fact, that which is claimed.

Work - the process of performing a defined task or activity (e.g., research and development, field sampling, analytical operations, equipment fabrication).